**BS EN ISO 18113-4:2011**

*Incorporating corrigendum December 2011*

BSI Standards Publication

# In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling)

## Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2009)

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## National foreword

This British Standard is the UK implementation of EN ISO 18113-4:2011. It is identical to ISO 18113-4:2009. It supersedes BS EN ISO 18113-4:2009, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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**Compliance with a British Standard cannot confer immunity from legal obligations.**

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2011.

**Amendments/corrigenda issued since publication**

| Date | Text affected |
|---|---|
| 31 January 2012 | Implementation of CEN correction notice 9 November 2011: Corrected date of withdrawal in EN foreword |

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 18113-4

October 2011

ICS 11.100.10

Supersedes EN ISO 18113-4:2009

English Version

## In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2009)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 4: Réactifs de diagnostic in vitro pour auto-tests (ISO 18113-4:2009)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 4: Reagenzien für in-vitro-diagnostische Untersuchungen zur Eigenanwendung (ISO 18113-4:2009)

This European Standard was approved by CEN on 20 September 2011.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

The CEN correction notice 9 November 2011 provided a revised English language text, incorpotating the following editorial corrections: Changed date of withdrawal in the second paragraph of the Foreword.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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## Foreword

This document (EN ISO 18113-4:2011) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 “In vitro diagnostic medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2012, and conflicting national standards shall be withdrawn at the latest by October 2014.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 18113-4:2009.

This new edition contains a revised Annex ZA.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

**Endorsement notice**

The text of ISO 18113-4:2009 has been approved by CEN as EN ISO 18113-4:2011 without any modification.

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# Annex ZA
(informative)

## Relationship between this European Standard and the Essential Requirements of the EU Directive 98/79/EC on "in vitro Diagnostic Medical Devices"

This European Standard has been prepared under a mandate given to CEN by the European Commission to provide a means of conforming to the Essential Requirements of the New Approach Directive 98/79/EC on "*in vitro* Diagnostic Medical Devices".

Once this European Standard is cited in the Official Journal of the European Union under that Directive and has been implemented as national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this European Standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

**Table ZA.1 — Correspondence between this European Standard and European Directive 98/79/EC**

| Clauses of this European Standard | Essential Requirements (ERs) of Directive 98/79/EC | Qualifying comments/Notes |
|---|---|---|
| 4.3, 6.1, 7.3, 7.11 | B.7 | These clauses only cover the second sentence of ER B.7, namely the labelling requirements. |
| 4.2, 4.3, 5, 6, 7 | B.8.1 | Presumption of conformity with ER B.8.1 also requires compliance with clauses 4.1, 4.2.1 and 4.6 of EN ISO 18113-1. |
| 5.8, 6.8, 7.9 | B.8.3 | **NOTE 2** |
| 5.1, 6.2 | B.8.4(a) | **NOTE 1** |
| 5.2, 5.3, 6.3.1, 6.4 | B.8.4(b) | |
| 5.2.2, 6.3.2 | B.8.4(d) | Full compliance to ER B.8.4(d) requires the use of EN 980, clause 5.4, symbol (LOT). |
| 5.7, 6.7 | B.8.4(e) | |
| 5.5, 6.5 | B.8.4(g) | |
| 5.6, 6.6 | B.8.4(h) | |
| 5.8, 6.8 | B.8.4(j) | **NOTE 2** |
| 5.4 | B.8.4(k) | |
| 5.4, 7.3 | B.8.5 | |
| 5.2.2, 6.3.2 | B.8.6 | |
| 7.1, 7.2, 7.3, 7.8, 7.9 | B.8.7(a) | Presumption of conformity with ER B. 8.7(a) requires also compliance with clause 4.5 of EN ISO 18113-1.<br>**NOTE 1, NOTE 3** |
| 7.5 | B.8.7(b) | |
| 7.8 | B.8.7(c) | |
| 7.6 | B.8.7(e) | |
| 7.10 | B.8.7(f) | |
| 7.11 | B.8.7(g) | |



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| Clauses of this European Standard | Essential Requirements (ERs) of Directive 98/79/EC | Qualifying comments/Notes |
|---|---|---|
| 7.4, 7.7 | B.8.7(h) | |
| 7.12 | B.8.7(k) | **NOTE 3** |
| 7.6 | B.8.7(m) | |
| 7.9 | B.8.7(s) | |
| 7.13, 7.14, 7.15, 7.16, 7.17 | B.8.7(t) | |

**NOTE 1** In the European Union, the name and address of the manufacturer's "EC Authorized representative" is required on the outer container label or in the instructions for use, if the legal manufacturer is not located within the European Union.

**NOTE 2** Essential Requirement B.8.3 of Directive 98/79/EC should be consulted for a comprehensive list of the information required.

**NOTE 3** Essential Requirement B.8.7 of Directive 98/79/EC should be consulted for a comprehensive list of the information required.

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 18113-4 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*

ISO 18113 consists of the following parts, under the general title In vitro *diagnostic medical devices — Information supplied by the manufacturer (labelling)*:

— *Part 1: Terms, definitions and general requirements*

— *Part 2:* In vitro *diagnostic reagents for professional use*

— *Part 3*: In vitro *diagnostic instruments for professional use*

— *Part 4:* In vitro *diagnostic reagents for self-testing*

— *Part 5:* In vitro *diagnostic instruments for self-testing*


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